EXHIBIT 1

U. S. Department of Justice
Drug Enforcement Administration
Office of Chief Counsel

www.dea.gov

November 11, 2022

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Dr. Oberheiden:

We are extending an invitation to Ascent Pharmaceuticals Inc. (Ascent) to reconcile the discrepancies in the controlled substance audits found by the Drug Enforcement Administration (DEA) New York Division Long Island District Office. Please provide your client's response by November 25, 2022. It is our intent to proceed forward in the compliance investigation using the most accurate information possible and to draw it to a close based on the best understanding of the facts.

As you are aware, on May 3, 2022, DEA began an accountability audit for the period of close of business December 31, 2020, to beginning of business May 3, 2022, for methylphenidate (including 5 mg, 10 mg, and 20 mg finished forms), oxycodone raw material, and hydrocodone raw material.

Of note, DEA found at the packaged stage a discrepancy in methylphenidate 20 mg of +4,413,600 tablets (+12.481%).

Additionally, on August 1, 2022, DEA began an accountability audit for the period from close of business December 31, 2020, to close of business August 1, 2022, for hydrocodone/acetaminophen (APAP) 5/325 mg, oxycodone/APAP 10/325 mg, oxycodone 15 mg, oxycodone 30 mg, mixed amphetamine salts 5 mg, and mixed amphetamine salts 30 mg.

Noteworthy here, DEA found the following discrepancies:

- At the blend stage: oxycodone 15 mg and 30 mg of -56.7978 kg (-4.83%)
- At the packaged stage: mixed amphetamine salts 30 mg of -2,670,754 tablets (-7.27%).
- At the shipping (bottles) stage:
  Hydrocodone/APAP 5/325 mg 100 count (ct): +186,716 bottles (+10.23%)
  Hydrocodone/APAP 5/325 mg 500-ct bottles: +3,928 bottles (+26.58%)
  Oxycodone/APAP 10/325 mg 100-ct bottles: +77,169 bottles (+25.28%)
  Oxycodone/APAP 10/325 mg 500-ct bottles: +14,241 bottles (+10.84%)
  Oxycodone 15 mg 100-ct bottles: -19,637 bottles (-12.85%)
  Oxycodone 15 mg 500-ct bottles: +6,313 bottles (+37.69%)
  Oxycodone 15 mg 1000-ct bottles: +60 bottles (+100%)
  Oxycodone 30 mg 100-ct bottles: +18,859 bottles (+11.69%)
  Oxycodone 30 mg 500-ct bottles: -688 bottles (-4.69%)

Oxycodone 30 mg 60-ct bottles: -2 bottles (-100%)
Mixed amphetamine salts 5 mg 100-ct bottles: +2,950 bottles (+3.91%)
Mixed amphetamine salts 30 mg 100-ct bottles: +27,122 bottles (+7.99%)

Also, on and between August 1, 2022, and August 3, 2022, DEA and Ascent performed a closing inventory. As part of the closing inventory, DEA sought to determine the amount of finished-form controlled substance products that Ascent had on hand on August 1, 2022. To make this calculation, Ascent provided a biennial inventory dated December 31, 2020, to DEA investigators that showed (after interpretation) quantities of controlled substances, as indicated below.

Finished Product:	Quantity:
Hydrocodone 5/325 mg 100-ct bottles	356
Hydrocodone 5/325 mg 500-ct bottles	32
Oxycodone 10/325 mg 100-ct bottles	1,515
Oxycodone 10/325 mg 500-ct bottles	195
Oxycodone 15 mg 100-ct bottles	287
Oxycodone 15 mg 500-ct bottles	143
Oxycodone 15 mg 1,000-ct bottles	60
Oxycodone 30 mg 100-ct bottles	101
Oxycodone 30 mg 500-ct bottles	40
Oxycodone 30 mg 60-ct bottles	2
Amphetamine salts 5 mg 100-ct bottles	0
Amphetamine salts 30 mg 100-ct bottles	0

Later, on October 20, 2022, Mr. Venkatasubramanian Jayaraman, on behalf of Ascent, indicated that the biennial inventory was at zero for all products above and that Ascent does not produce oxycodone 15 mg 1,000-ct bottles and oxycodone 30 mg 60-ct bottles.

Finally, on August 3, 2022, DEA and Ascent finished the closing inventory, which Mr. Jayaraman signed, attesting that only raw materials and no finished products were on-site on August 1, 2022. However, on October 21, 2022, Ascent provided documents in regards to the above-referenced accountability audit period ending August 1, 2022, that showed "Inventory/Not Shipped" quantities of 912 hydrocodone 5 mg 100-ct bottles and 216 oxycodone 15 mg 100-ct bottles.

Conflicting information such as this—as well as the discrepancies uncovered in DEA's audits discussed above—gives DEA cause to further vet the information disclosed by Ascent and to expect honest, adequate explanations.

Thus far, when DEA has presented Ascent with variances like those noted above, Ascent has produced additional documents, including batch records and DEA Forms 222. This is concerning for multiple reasons. First, these documents on their face either do not explain the variances or contradict previously disclosed information. Second, it is not clear why such documents were not provided to DEA when DEA began its accountability audits. Please note that the regulations under the Controlled Substances Act require inventories and records to be readily retrievable and available for inspection upon request by DEA. *See* 21 C.F.R. § 1304.04(f). This is an excellent opportunity to

explain these issues and to clarify any misunderstandings.

In your response, please:

1. Indicate whether Ascent concurs with the above audit calculations and discrepancies. If Ascent does not concur to any extent, please provide Ascent's calculations and any records relied on to reach those calculations in an organized manner. Please ensure that any such records are clearly labeled. And please ensure that if you provide new calculations, they clearly identify the records upon which you are relying.

2. Explain how products that Ascent does not produce would be recorded in its biennial inventory. Please also indicate whether Ascent concurs with the biennial inventory quantities. If Ascent does not concur, please clearly describe how Ascent interpreted these records to calculate its product quantities.

3. Provide an explanation for the contradictory biennial inventory quantities and closing inventory quantities.

If you have any questions regarding this matter, please contact DEA's Office of Chief Counsel, Edward O. Siclari at Edward.O.Siclari@dea.gov or David Locher at David.M.Locher@dea.gov.

Sincerely,

EDWARD SICLARI

Digitally signed by EDWARD SICLARI
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Edward O. Siclari
Attorney
Office of Chief Counsel
U.S. Drug Enforcement Administration